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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,150	01/26/2006	Rolf Mueller	3712161-001 (91936US-PCT)	2740
24573	7590	07/20/2010	EXAMINER	
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			BEKKER, KELLY JO	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,150	Applicant(s) MUELLER ET AL.	
	Examiner KELLY BEKKER	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,8,14,15 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,8,14,15 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/14/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments made June 14, 2010 have been entered.
Claims 1, 6, 8, 14, 15, and 19-23 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2010 has been entered.

Priority

This application is a national stage entry of International Application No. PCT/CH03/00832, filed December 19, 2003, which claims priority to German Application No. 102609632, filed December 20, 2002. The copy of the certified copy of the priority has been filed with the instant Application, however, it is noted that the Foreign Application is not in English and thus it is unclear as to if the instant claims have priority to the Foreign Application.

Claim Rejections - 35 USC § 112 1st Paragraph

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 112 first paragraph rejections of claim 18 has been withdrawn as the claim has been canceled.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 recites, "The starch matrix has a network, which is formed by homocrystallites and/or heterocrystallinities". Although the specification discloses a candy with homocrystallites and/or heterocrystallinities networks, the specification does not disclose how such a network is made. The specification does not disclose the processing parameters or composition needed to make a network with the instantly claimed properties. One of ordinary skill in the art would not know the process required to produce such a product.

Response to Arguments, 112 first paragraph

Applicant's arguments regarding the remaining 112 first paragraph rejections have been fully considered but they are not persuasive.

Applicant argues that at least the methods section and working examples of the specification, together with the knowledge in the art evidenced by WO 03/035026 and WO 03/035044 enable a person skilled in the art to make the candy claimed.

Applicant's argument is not convincing as (1) the method and examples section in the specification provide for the use of common methods and do not specify or even suggest the steps critical in order to produce the instantly claimed product; (2) The cited references which are referred in the remarks and specification have any been considered only for their abstract as the references are not in English; and (3) as discussed above, the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 112 2nd Paragraph and 101

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 112 first paragraph rejections of claim 18 has been withdrawn as the claim has been canceled.

The 112 second paragraph rejections due to the terms "VS" and "NS", the recitation "wherein the candy has at least one retrogradation-inhibiting material,

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especially glycogen or a dextran with a degree of branching of more than 0.05” and “the candy contains a proportion of 3-15% of network capable starch, the proportion in percent in a), b) and c) being based on the dry weights and on the proportion of starch present” have been withdrawn in light of applicant’s amendments made June 14, 2010.

The following 112 first paragraph rejections remain:

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites, “The starch matrix has a network, which is formed by homocrystallites and/or heterocrystallinities”. It is unclear as to how such a network is made. The processing parameters and/or composition needed to make a network with the instantly claimed properties is unclear.

Response to Arguments, 112 second paragraph

Applicant's arguments regarding the remaining 112 second paragraph rejections have been fully considered but they are not persuasive.

Applicant argues that a person skilled in the art would understand a network of homocrystallites and/or heterocrystallites and that the terms would be understood. Additionally, applicant argues that the process limitations as shown in the specification and as evidenced by WO 03/035026 and WO 03/035044 would provide for clear meanings. Applicant’s argument is not convincing as applicant has not pointed to any meanings or definitions which make the unclear terms definite; Applicant merely states that the claims are definite without any supporting rationale. As discussed above, the claims are unclear and the cited references which are referred to in the remarks and specification have not been considered only for their abstract as the references are not in English.

Claim Objections

The objection to claim 8 for the typographical error "dextran" has been withdrawn in light of applicant's amendments made June 14, 2010.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6, 8, 14, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chakraborty et al (US 5262191) in view of Fennema (Food Chemistry Third Edition pages 128, 129, and 201) and as evidenced by Hui (ed.) Handbook of Food Science, Technology, and Engineering Volume 1 page 3-8.

Chakraborty et al (Chakraborty) teaches of a jelly candy based on a starch mix (abstract). Since the starch candy takes the form of candy, the starch mix is a starch matrix (a matrix is defined as something that takes form or develops). Chakraborty teaches that the candy contains about 5-67.5% corn syrup, which is a sugar type and about 2.5-60% sweeteners, including fructose, which is a retrogradation inhibiting material, and 0% plasticizer (Chakraborty Column 5 lines 13-42 and Applicant's Specification pages 17-18). Chakraborty teaches that the candy is formed in a common manufacturing method wherein the preparation of a starch mix pre-product is used (Column 6 lines 10-42). Chakraborty teaches that the starch mix includes 10-60% of a acid converted or hydrolyzed high amylose starch, with an amylose greater than 50%, derived from wheat, corn, and barley (Column 2 line 9 through Column 3 line 68 and Column 4 lines 1-12). Chakraborty teaches that the starch mix includes 40-90% of a low amylose starch (amylose 5-35%) derived from potato, tapioca, rice, corn, and wheat which is thin-boiled, (i.e. reduced dpn) or oxidized (Column 4 lines 1-61). Chakraborty teaches that the candy contains a total of 1-25% starch and 20-75% water (Column 5 lines 5-12 and 58-62), and thus, 0.1-15% of a network starch. Note: Chakraborty teaches that a waxy starch is not preferable as the low amylose starch (Column 4 lines 21-25).

Regarding the starch matrix as having a network that is homocrystallinities and/or heterocrystallinities, since Chakraborty teaches of a starch matrix substantially the same

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as the instantly claimed starch matrix one of ordinary skill in the art at the time the invention was made would expect that the starch matrix taught by Chakraborty inherently have the same properties of the instantly claimed starch matrix, including having a network of homocrystallinities and/or heterocrystallinities, absent any clear and convincing arguments and/or evidence to the contrary.

Chakraborty is silent to the degree of polymerization (DP) of the first starch as more than 1000 and the second starch as less than 300 as recited in claims 1 and 23, preferably wherein the first starch has a DP of greater than 1000 and/or the second starch has a DP of less than 50 as recited in claim 14, or less than 100 as recited in claim 22 and to the second starch being capable of forming a microcrystalline crosslinked network with the first starch as recited in claims 1 and 23.

Fennema teaches that it was known to modify starches depending on the desired affect of the starch in the final food product (page 201). Fennema teaches that less conversion resulting in a higher DP provides for ability of the starch to produce viscosity and prevent sugar crystallization and that greater conversion resulting in a lower DP provides for enhanced sweetness and flavor enhancement (pages 128-129 and Table 3.7). Fennema teaches that a starch with a DE of 20-60 and thus a DE of about 1.6-5 has a mild sweetness and rapid dissolvability (page 129).

As evidenced by Hui ed. (Handbook of Food Science, and Technology, and Engineering page 3-8) amylose from maize and wheat starches was known to have a DP of 200-1200 and amylose from potato or tapioca starches was known to have a DP of 1000-6000.

Regarding the DP of the first starch as more than 1000, as Chakraborty teaches that the first starch is made from potato or tapioca starch and as evidenced by Hui's showing that potato and rice starches were known to have a DP of 1000-6000, one of ordinary skill in the art at the time the invention was made would expect that the first starch as taught by Chakraborty have a DP of about 1000-6000. Furthermore, one of ordinary skill in the art would have been motivated to vary the DP of the starch depending on the final product desired, as was commonly done in the art as taught by Fennema. For example, it would have been obvious to one of ordinary skill in the art to

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use a starch with a greater DP in order to form a final candy in which the sugar did not crystallize over time as taught by Fennema. To adjust the DP of starch based upon the known effects of DP within the final product would have been obvious and routine determination.

Regarding the DP of the second starch as less than 300, preferably wherein the second starch has a DP of less than 100 or less than 50 and the second starch being capable of forming a microcrystalline crosslinked network with the first starch, as Chakraborty teaches that the second starch is made from corn or wheat starch and as evidenced by Hui's showing that corn and wheat starches were known to have a DP of 200-1200, one of ordinary skill in the art at the time the invention was made would expect that the second starch as taught by Chakraborty have a DP of about 200-1200. Furthermore, one of ordinary skill in the art would have been motivated to vary the DP of the starch depending on the final product desired, as was commonly done in the art as taught by Fennema. For example, it would have been obvious to one of ordinary skill in the art to use a starch with a lower DP, such as from about 1.6-5, in order to form a final candy in which the flavor and sweetness was enhanced as taught by Fennema. To adjust the DP of starch based upon the known effects of DP within the final product would have been obvious and routine determination. Furthermore, as Chakraborty teaches of starches as instantly claimed, one of ordinary skill in the art would expect that the starches have substantially the same properties, including the second starch being capable of forming a microcrystalline crosslinked network with the first starch, as the instantly claimed starch.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chakraborty et al (US 5262191) in view of Fennema (Food Chemistry Third Edition pages 128, 129, and 201) and as evidenced by Hui (ed.) Handbook of Food Science, Technology, and Engineering Volume 1 page 3-8, further in view of Igoe (Dictionary of Food Ingredients page 133).

Chakraborty teaches of a candy comprising about 25-75% sweeteners, about 20-75% water, about 1-25% starch, about 0-10% flavoring and coloring and additional

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ingredients including humectants (Column 5 lines 5-62), however is silent to the candy as including 3-30% plasticizers as recited in claim 15.

Igoe teaches sorbitol is a humectant that is a polyol with good solubility in water that maintains good moistness in candy. Igoe teaches that sorbitol is 60% as sweet as sugar and is used in low calorie foods. Refer to page 133.

Regarding the candy as including 3-30% plasticizers, Chakraborty teaches that the composition includes about 56-100% sweeteners, starch, flavoring, coloring and water and thus 0-34% other ingredients including humectants, however is silent to the humectant used. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sorbitol, which is a humectant in plasticizer, as the 0-34% humectant as taught by Chakraborty in order to form a moist candy as taught by Igoe.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chakraborty et al (US 5262191) in view of Fennema (Food Chemistry Third Edition pages 128, 129, and 201) and as evidenced by Hui (ed.) Handbook of Food Science, Technology, and Engineering Volume 1 page 3-8, further in view of Yotka et al (US 5458892).

Chakraborty teaches of a candy comprising about 25-75% sweeteners including aspartame, about 20-75% water, about 1-25% starch, about 0-10% flavoring and coloring and additional ingredients including humectants (Column 5 lines 5-62), however is silent to the candy as including retrogradation inhibiting material selected from the group consisting/comprising of glycogen and a dextrin with a degree of branching of more than 0.05 as recited in claims 19 and 21, preferably more than 0.3 as recited in claim 20.

Yotka et al (Yotka) teaches that highly branched indigestible dextrin, such as Fibersol 2, is added to confectionary compositions, including gummy type candies, wherein the ingredient does not induce dental cavities, can be consumed by diabetics, does not contribute to calories, does not cause gastrointestinal disturbances, acts as a bulking and sweetening agent, is water soluble, has properties like fiber, improves

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texture, flavor, and shelf life, replaces conventional sweeteners, stabilizes aspartame, and provides for faster flavor release (Column 1 lines 17-58, Column 2 lines 14-50, Column 5 lines 1-46, Column 6 lines 13-62, and Example 196).

Regarding the candy as including retrogradation inhibiting material selected from the group consisting of glycogen and a dextrin with a degree of branching of more than 0.05, preferably more than 0.3, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include dextrin, with a high degree of branching, in the candy composition of Chakraborty in view of Yotka. One would have been motivated to do so in order to gain the benefits of highly branched dextrin, including improved texture, flavor, and shelf life, the stabilization of aspartame, as sweetener in the composition as taught by Chakraborty, and to provide for faster flavor release, as taught by Yotka. Note: As the dextrin taught by Yotka is highly branched, one of ordinary skill in the art would expect the dextrin to have a degree of branching above 0.05, preferably 0.3 as instantly claimed.

Response to Arguments

Applicant's arguments filed June 14, 2010 have been fully considered but they are not persuasive.

Applicant argues that the claimed product is surprising and unexpected rubber elastic properties compared to traditional starch candies. Applicant's argument is not convincing as the statement makes a comparison between traditional starch candies and not the prior art and thus is not comparing the invention to the closest prior art of record; as Chakraborty teaches the starch is directly related to texture (Column 1 lines 9-19) and thus to modify the starch and obtain a modified texture would not be unexpected; and as applicant has provided no evidence to support unexpected results. It is noted that the specification provides a similar statement and supports this statement with the compositions listed in table 1. This table provides for insufficient evidence as it is unclear as to which samples are encompassed within the invention and which are not; it appears that none of the samples are encompassed by the invention as the table only shows the inclusion of one starch, the NS starch and the invention claims

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two starches; similarly the DPn values in the table are 20 and 100 and the claimed values are more than 1000 and less than 300.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., network density) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the references do not teach of the newly added limitations. Applicant's argument is not convincing; the limitations have been addressed in the rejection above.

Applicant argues that as Chakraborty teaches of depositing the starch candy into molds, the starch must be included in low amounts, i.e. typically up to 5%, or when higher amounts are used a retrograde starch must be used and thus, the starch of Chakraborty would have a DPn of less than 1000. Applicant's argument is not convincing as Chakraborty teaches of as low as 1% starch and this does not require the greater amount of starch and thus the retrograde starch as argued; as it is unclear as to how applicant's reasoning would lead to the specific conclusion that the starch of Chakraborty must be less than 1000 (i.e. how did applicant determine the specific DPn value); and as the instant invention is also disclosed as formed by molding.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY BEKKER whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kelly Bekker/
Examiner
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